LABEL, IN PART: "Bethiamin A Brand of Thiamine Hydrochloride (B_1) * * * For Intramuscular or Intravenous Administration," "Calcium Gluconate, 10%," or "Livitamin Represents in one Fluid Ounce * * * Thiamine Hydrochloride (B_1) 3 mg. in 100 cc. 10.14."

NATURE OF CHARGE: *Bethiamin.* Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance by reason of the presence of viable mold; and, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be suitable and appropriate for intramuscular and intravenous administration, a use which requires a sterile product, whereas the article was unsuitable and inappropriate for intramuscular and intravenous administration since it was unsterile by reason of contamination with viable mold.

Calcium gluconate. Adulteration, Section 501 (d), boric acid had been substituted in part for "Calcium Gluconate Ampuls," in that the article purported to be and was represented as "Calcium Gluconate Ampuls," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and the article contained boric acid, whereas "Calcium Gluconate Ampuls," the specifications of which are set forth in the Pharmacopoeia, do not contain boric acid.

Livitamin. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that it was represented to contain 3 milligrams of thiamine hydrochloride in 1 fluid ounce and 10.14 milligrams of thiamine hydrochloride in 100 cc., whereas it contained less thiamine hydrochloride than represented.

DISPOSITION: March 4, 1947. A plea of guilty having been entered, the court imposed a fine of $1,000 on each of the 3 counts of the information.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2205. Adulteration and misbranding of estrogenic hormones. U. S. v. Organics, Inc., and Lawrence Hicks. Plea of guilty on behalf of corporation; plea of not guilty by individual defendant. Fine of $500 and costs against corporation; individual defendant found not guilty. (F. D. C. No. 22009. Sample Nos. 15452–H, 52460–H.)

INFORMATION FILED: April 8, 1947, Northern District of Illinois, against Organics, Inc., Chicago, Ill., and Lawrence Hicks, president of the corporation.

ALLEGED SHIPMENT: On or about May 29 and July 8, 1946, from the State of Illinois into the States of Ohio and Michigan.

PRODUCT: Examination showed that the product contained 60 percent of the labeled claim for estrogenic activity, or 6,000 International Units per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that it purported and was represented to possess a physiological activity equivalent to 10,000 International Estrone Units per cubic centimeter, whereas it possessed a physiological activity equivalent to less than 10,000 International Estrone Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Natural Estrogenic Hormones Isolated from Gravid Equine Urine consisting principally of Estrone * * * 10,000 I. U. per cc." was false and misleading.

DISPOSITION: June 24, 1947. A plea of guilty having been entered on behalf of the corporation, and a plea of not guilty having been entered by the individual, the court imposed a fine of $500 and costs against the corporation and found the individual defendant not guilty.

2206. Adulteration and misbranding of P-Drine Sulfathiazole, Elixir Feotone, Sulfedol, isotonic solution ephedrine gluconate, and isotonic ephedrine solution. U. S. v. Benjamin Volk (Summit Pharmaceutical Co.). Plea of guilty. Fine, $50. (F. D. C. No. 21469. Sample Nos. 3270–H, 15790–H, 43282–H to 43284–H, incl.)

INFORMATION FILED: On or about May 20, 1947, District of New Jersey, against Benjamin Volk, trading as the Summit Pharmaceutical Co., at Morristown, N. J.

*See also No. 2204; veterinary preparations, Nos. 2241, 2242.

ALLEGED SHIPMENT: On or about February 3 and 6, 1946, from the State of New Jersey into the States of Maryland and Michigan.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possses, in that there was less ephedrine hydrochloride in the *P-Drine Sulfathiazole*, less alcohol and ferrous sulfate in the *Elixir Feotone*, less desoxyephedrine hydrochloride in the *Sulfedol*, and less ephedrine alkaloid in the *isotonic solution ephedrine gluconate* and the *isotonic ephedrine solution* than the respective articles were represented to contain.

Misbranding, Section 502 (a), the following label statements were false and misleading: (*P-Drine Sulfathiazole*) "Ephedrine Hydrochloride 1 Percent," (*Elixir Feotone*) "Each fluid ounce contains Alcohol 5%, Ferrous Sulphate—20 Grains," (*Sulfedol*) "Desoxyephedrine Hydrochloride 0.125%," and (*isotonic solution ephedrine gluconate* and *isotonic ephedrine solution*) "Contains Ephedrine Alkaloid 1%."

DISPOSITION: June 6, 1947. A plea of guilty having been entered, the court imposed a fine of $5 on each of the 10 counts of the information.

2207. Adulteration of thiamine hydrochloride tablets. U. S. v. Rexall Drug Co. (United-Rexall Drug Co.). Plea of nolo contendere Fine, $1,500 (F. D. C. No. 23279. Sample Nos. 62901–H, 62902–H, 81514–H.)

INFORMATION FILED: August 12, 1947, Eastern District of Missouri, against the Rexall Drug Co., a corporation, formerly trading as United-Rexall Drug Co., St. Louis, Mo.

ALLEGED SHIPMENT: Between the approximate dates of November 7, 1945, and June 21, 1946, from the State of Missouri into the States of California and Oregon.

LABEL, IN PART: "Thiamine Hydrochloride (Vitamin B_1) United Drug Co. Boston—St. Louis."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality fell below the official standard since it contained glass.

DISPOSITION: September 29, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $500 on each of the 3 counts of the information.

2208. Adulteration of physiological salt solution. U. S. v. 178 Vials * * *. (F. D. C. No. 23501. Sample No. 87813–H.)

LIBEL FILED: July 17, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about June 12, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 178 vials of *physiological salt solution* at Hoboken, N. J.

LABEL, IN PART: "100 cc. Size Sterile Physiological Salt Solution * * * Parenteral."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Physiological Salt Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 9, 1947. Default decree of condemnation and destruction.

2209. Adulteration of epinephrine hydrochloride injection. U. S. v. 120 Vials * * *. (F. D. C. 23691. Sample No. 66340–H.)

LIBEL FILED: September 9, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 18, 1947, by Lederle Laboratories Division, American Cyanamide Co. (Shipment made from Pearl River, N. Y.)

PRODUCT: 120 1-ounce vials of *epinephrine hydrochloride injection* at Norristown, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Hydrochloride Injection," a drug the